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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,738	03/06/2006	Joshua E. Medow	09820283/P03355US	8705
60961 7590 11/19/2009 Intellectual Property Dept./Dewitt Ross & Stevens Wisconsin Alumni Research Foundation 2 East Mifflin Street, Suite #600 Madison, WI 53703-2865				
EXAMINER				
WIEST, PHILIP R				
ART UNIT		PAPER NUMBER		
3761				
NOTIFICATION DATE		DELIVERY MODE		
11/19/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket-ip@dewittross.com

Office Action Summary

Application No.

10/570,738

Applicant(s)

MEDOW ET AL.

Examiner

Philip R. Wiest

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-16, 18-21, 58 and 60-75 is/are pending in the application.
- 4a) Of the above claim(s) 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-16, 18-21, 58 and 60-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

In the reply filed 7/1/09, applicant amended claim 1 and cancelled claims 17, 22-25, 27-39, 52-57, and 76-77. Claims 1-6, 8-16, 18-21, 58, and 60-75 are currently pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5, 6, 8-15, 17-21, 58, 60, 62, and 64-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drevet et al. (US 5,643,195) in view of Burbank (US 6,565,525).

1. With respect to Claims 1, 2, and 58, Drevet discloses a fluid shunt for regulating the flow of cerebrospinal fluid ("CSF"), said shunt comprising an inlet port, an outlet port, a fluid passageway between said inlet and outlet, and a valve 14 situated between the inlet and outlet. The valve defines a drain port between an upstream side and a downstream side (6 and 13) of the fluid passageway. The device further comprises a piston having a piston face defined on the upstream side of the passageway and being displaceable to actuate the valve (see Abstract). The fluid bearing on the piston face will actuate the valve and allow fluid communication between the inlet and outlet ports.

A portion of the piston face is defined by a deformable diaphragm 9. The deformable diaphragm is connected to a spring 17 such that the diaphragm and spring provide a biasing force to maintain the valve in a closed state unless a sufficient pressure differential is provided.

2. With respect to Claim 5, 6, 11, and 64, the piston is displaceable along a piston travel axis, and fluid flowing through the valve between the upstream and downstream sides (6 and 13) flows substantially perpendicular to said axis. The piston further comprises a piston tail opposite the piston face, and the downstream side of the fluid passage opens onto the piston only at the intermediate length of the piston. The piston tail is opposite the piston face, and the upstream side of the fluid passage opens onto the piston tail (see Figure 1). When a sufficient pressure differential across the diaphragm is present, the diaphragm will displace the piston along the travel axis and open the valve.

3. With respect to Claim 12-15, 60, and 62, Drevet further discloses that the deformable diaphragm 9 includes a fluid side 7 bounded by the upstream side 7 of the fluid passageway, and an opposite side isolated from the fluid passage. The diaphragm 9 is biased by a spring 17. The opposite side is isolated from both the upstream and downstream sides of the fluid passage by the diaphragm 9, and the pressure of the spring 17 is capable of being adjusted by means of a screw 18 (see Figure 1). When a sufficient pressure differential across the diaphragm is present, the diaphragm will displace the piston along the travel axis and open the valve.

4. With respect to Claims 18, 20, 21, and 68-70, the device is designed to drain CSF from the cranium to a resorption site, such that the peritoneum (Column 1, Lines 5-17).
5. With respect to Claim 19 and 71, the outlet portion 4 has an extended flexible catheter 5 extending therefrom.
6. Drevet, however, does not specifically teach that the piston comprises a cutout defined therein, the cutout being alignable with the drain port when the piston is displaced such that the valve may be opened.
7. Burbank et al. (hereafter 'Burbank') teaches a valve assembly comprising a plurality of pistons that are displaceable to control flow through the system (see Figures 4-6). The pistons have lumens (i.e. cutouts) 112b defined on the surface thereof in order to allow fluid flow through the system only when the piston is in a certain position. When the piston is in the original position, the cutout does not line up with the drain port, such that fluid cannot flow through the system (see Figure 5). Therefore, fluid communication is only established when the piston is in the advanced position (see Figure 6). Additionally, the *relative pressures of fluid on either side of the piston have no effect on the position of the piston* (the piston's position is determined solely by the actuating means). Pistons having drainage lumens extending therethrough are well known in the art of medical fluid flow systems because they provide simplistic means for allowing and preventing fluid flow through a system. Therefore, it would have been

obvious to one of ordinary skill in the art at the time of invention to modify the piston-controlled CSF flow regulating system of Drevet with Burbank's piston having a cutout therein, in order to provide a well-known, alternate means for controlling fluid flow between the inlet and the outlet of a fluid shunt.

8. Claims 3, 4, 16, 61, and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drevet in view of Burbank, and further in view of Drake et al. (US 5,192,265). Drevet and Burbank reasonably suggest a flow-regulating CSF shunt substantially as claimed (see rejection above), but does not specifically disclose that the diaphragm comprises a fluid side in contact with the upstream chamber and a gas side, opposite the fluid side, bounded by a regulatable gas chamber. Drake discloses an adjustable CSF shunt comprising a fluid passageway 5 surrounded by a pair of flexible walls (i.e. diaphragms). A gas chamber 9 is disposed on the opposite side of the flexible sheets from the fluid passageway, such that pressure is applied to the diaphragms to form a valve (Figure 1). When a low pressure differential exists between the inlet and the outlet, the valve is closed. When a pressure differential between the inlet port 7 and outlet port 8 is present, however, the diaphragms will deform, allowing fluid to pass through the fluid passageway. Furthermore, Drake discloses that the gas pressure in the gas chamber 9 may be manually adjusted by moving a ball 14 through the gas pressure control means 10 (Column 3, Lines 34-44). The use of a gas source therefore allows a pressure to be applied to the opposite side of the diaphragm, thus eliminating the need for a spring member to apply pressure to the diaphragm.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the flow control device of Drevet and Burbank with the use of a gas source to apply pressure to the opposite side of the diaphragm in order to provide a well known, alternate means for controlling the pressure differential between the inlet and outlet of a CSF shunt.

9. Claims 72-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drevet in view of Burbank, and further in view of Zinger et al. (US 6,379,340). Drevet and Burbank reasonably suggest the device substantially as claimed. Specifically, Drevet teaches the use of a piston that moves in response to a pressure differential, and Burbank suggests the use of a piston having a cutout therein that lines up with the drain port. Drevet and Burbank, however, do not specifically teach that the cutout of the piston moved along a curved path between the first and second positions. Zinger et al. (hereafter Zinger) teaches a flow control device comprising a piston having a cutout 25 therein that extends along the wall of the piston, thereby defining a drain port (see Figure 4). The device may be rotated in order to establish fluid flow between the inlet 14 and the outlet 16 of the flow path. The rotational valve of Zinger therefore performs the same function as the axially-displaceable piston Burbank, except that it is displaced rotationally instead of axially. However, it has been held that substituting equivalents that are known for the same purpose does not constitute a patentable improvement in the art (see MPEP § 2144.06). Rotationally-displaced fluid valves having cutouts extending therethrough, such as that of Zinger, are commonly used in the art (see also

Wilson et al. – US 5,540,668). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the fluid control device of Drevet and Burbank with the rotationally-displaceable valve actuator of Zinger in order to provide a well-known, equivalent means for controlling fluid flow between an inlet and an outlet.

Response to Arguments

Applicant's arguments filed 7/1/09 have been fully considered but they are not persuasive. Applicant argues that the combination of Drevet with Burbank is improper.

First, applicant argues that Burbank's manually activated valve is not compatible with the system of Drevet because Burbank's piston is manually activated. This argument has not been found persuasive because Drevet clearly teaches the use of a flexible member to activate in a vertical direction. If the piston of Drevet was replaced with Burbank's cutout piston, the device would still function in the same basic manner: once a sufficient pressure builds up in the first chamber, the flexible member would cause the cutout piston to move such that fluid communication is established between the first and second chambers. Even though Burbank's piston valve is activated manually, it still operates under the same basic principle of changes in vertical position. Pistons having cutouts therein to control fluid flow based on the position of the piston (such as that of Burbank) are well known in the art. It is the examiner's opinion that merely replacing the piston device of Drevet with a well known alternative fluid control means does not constitute a patentable improvement in the art.

Second, applicant argues that there is no motivation to modify Drevet's device with Burbank's piston cutout valve. This argument has not been found persuasive because Drevet clearly cites the need to eliminate the effect of downstream pressure in pressure-based flow control devices. Burbank's cutout piston provides an alternate means for selectively allowing flow through a medical fluid system wherein flow is strictly prevented when the piston is not in the activated position (i.e. the piston operates independently of fluid pressures and solely based on the activating means). Based on Drevet's desire to minimize the effects of fluid pressure *directly on the piston*, one of ordinary skill in the art at the time of invention would have expected a reasonable degree of success when replacing the piston of Drevet with Burbank's cutout piston arrangement, because doing so provides a means for ensuring that no flow occurs when the piston is not activated.

It is important to note that, although Drevet claims to address the issue of downstream pressure (p. 12 of applicant's arguments), Burbank's patent was filed five years after Drevet's patent. Had Burbank's device existed at the time of Drevet's invention, it is the examiner's position that Drevet would have recognized its cutout valve as an obvious alternative means for controlling fluid flow through a medical device.

Applicant also argues that there is no motivation to modify the Drevet and Burbank devices with Zinger's rotationally-oriented piston cutout valve. This argument has not been found persuasive. The use of cutout valves to selectively control fluid flow

is well known in the art, and Zinger's flow control device uses the same type of valve, except that the piston is displaced rotationally instead of axially. The examiner concedes that there are basic mechanical differences that prevent one type of valve from being *directly* swapped with another. However, one of ordinary skill in the art at the time of invention would have recognized these axial and rotational cut out valve systems as art-recognized equivalents, and would have possessed the capacity to rearrange the device of Drevet so that a rotational cutout valve can be used.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phil Wiest/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
16 November 2009